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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,341	06/19/2002	Dominique Marechal	065691	3896

22428 7590 05/27/2005

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EXAMINER	
SPEAR, JAMES M	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,341	MARECHAL ET AL.	
	Examiner	Art Unit	
	James M. Spear	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear

JAMES M. SPEAR
PRIMARY EXAMINER
AU 1618

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

The Amendments filed 01 March 2005 and 12 May 2005 have been entered.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Sackler et al US 5,672,360. The claims remain rejected for the reasons set forth in the office action mailed 01 December 2004.

3. Applicant's arguments filed 12 May 2005 have been fully considered but they are not persuasive. Applicants state that "Although Sackler et al discloses a composition having Eudragit RS 30 D and talc, Sackler et al does not suggest the use of hydrophobic silica." While applicants claim 1 recites a silica exhibiting a hydrophobic character in the sustained release coating layer, the claim does not limit the silica to a particular amount or range. The claim encompasses minor and major amounts of said compound in relation to the other elements claimed. It appears the silica is present for the "hydrophobic character it exhibits". The exhibits applicants submitted show talc to be practically insoluble in water and it therefore exhibits hydrophobic character. Given the variability in the effective amounts of silica and talc it is the position of this office that a particular amount of talc would impart the same hydrophobic characteristics to the Sackler et al composition as would an amount of silica to applicants' because the Sackler et al sustained release morphine beads are the same as applicants'. Both silica and talc are pharmaceutical excipients possessing glidant and anti-caking properties and applicants use as an apparent excipient does not constitute a patentable distinction. Sustained release is not considered a function of silica alone but a function of the

combination of coating components. The prior art reference teaches a silicon containing component exhibiting a hydrophobic character as do applicants. Silica and talc are both silicon containing minerals and equivalent excipients used in formulating the sustained release morphine sulfate microgranules. Applicants also state "the microgranules of the present invention exhibit the advantage of not requiring a protective coating of sustained release layer, contrary to Sackler et al." While Sackler et al discloses a protective coating for the sustained release layer in the example, this is not always required but optional. See column 10, lines 34-61. Applicants further state they do not require a heat treatment of the microgranules as in Sackler et al. While applicants may eliminate such a treatment, how a composition is made is not a basis for determining patentability of composition claims. The prior art clearly shows applicants' microgranules providing sustained release of morphine sulfate for over 24 hours.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackler et al US 5,672,360.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Sackler et al reference shows 24 hour sustained release morphine sulfate granules as explained above. The prior art does not show particular formulations and specific amounts of components as applicants' (% by mass), claims 20-23. The reference does show the various conventional excipients, plasticizers such as, triethyl citrate, column 9, line 63 through column 10, line 3, binders, lines 15-25, lubricants etc, column 11 through column 13. The reference further recognizes the significance of determining dissolution rates and serum levels of the morphine sulfate microgranules. Column 15, line 59 through column 16. Tables 3-25. To arrive at specific dissolution rates and serum levels for morphine sulfate would require different amounts of ingredients in formulations comprised of the same ingredients. Given such desired values for dissolution and serum levels of morphine sulfate one skilled in the art would readily determine particular formulations using conventional modified release components without undue experimentation.

It would have been obvious to one of ordinary skill in the art to modify the once a day dosage formulations of Sackler et al to specific ranges and amounts as disclosed in applicants' claims 11-23. The motivation being a desire to tailor the dosage form to

treat an individual's specific form of pain resulting in optimum pain relief for 24 hours or more and increased patient compliance.

Claims 1-23 are rejected.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272

0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James M. Spear

James M Spear
Primary Examiner
Art Unit 1618

May 25, 2005